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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/541,344

08/14/2006

Vaddu Venkata Narayana Reddy

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LADAS & PARRY LLP  
26 WEST 61ST STREET  
NEW YORK, NY 10023

EXAMINER

KATAKAM, SUDHAKAR

ART UNIT

PAPER NUMBER

1621

MAIL DATE

DELIVERY MODE

03/17/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/541,344	<b>Applicant(s)</b> REDDY ET AL.	
	<b>Examiner</b> Sudhakar Katakam	<b>Art Unit</b> 1621	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 05 July 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-44 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-44 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8/14/06</u> .   | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Information Disclosure Statement***

1. The examiner has considered applicant's Information Disclosure Statements of 14<sup>th</sup> Aug 2006. Please refer to the signed copies of the PTO-1449 forms attached herewith.

### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 9 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear from the claim language, whether the applicants intend to claim a arylamine or alkyl amines as resolving agents for the process. Proper correction is required.

### ***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claim 1-8 and 11-31 is rejected under 35 U.S.C. 102(b) as being anticipated by **Takuma et al** (EP 0 107 972 A1).

**Takuma et al** disclose a method for optical resolution of alpha-isopropyl-p-chlorophenylacetic acid (ICPA), also known as ( $\pm$ )-2-(4-chlorophenyl)-3-methyl butanoic acid (CPA), by using an optically active alpha-phenyl-beta-(p-tolyl)ethylamine (PTE) as an optical resolving agent [page 1, lines 1-8]. First, ICPA is reacted with (+)-PTE to form a salt. The amount of (+)-PTE is in a range of 0.5 to 1.0 mole based on 1 mole of ICPA [page 6, lines 12-14]. The temperature for the reaction is 40°C to 150°C. Next, the ICPA-PTE salt is crystallized in the solvent. The solvents are selected from lower alcohols, lower aliphatic ketones, mixtures with aromatic hydrocarbons, solvents may be used in a mixture with water, and the amount of solvent is preferably 1 to 15 times by weight [page 7, lines 5-22]. A temperature of crystallization is carried out at 0°C to 60°C. Next the crystallization salt crystal is separated from the mother liquor by means such as filtration. The crystal salt is preferred to decompose the salt into (+)-ICPA by acid (e.g. HCl, sulfuric acid) or alkali [page 8, lines 1-9]. When (-)-ICPA of high optical purity is required, this object can be attained by carrying out completely the same operation using (-)-PTE of not less than 95% in optical purity.

### ***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claims 1-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Takuma et al** (EP 0 107 972 A1) in view of **Yoneyoshi et al** (US 5,510,519).

The claims are further limited to the arylamine, wherein arylamine is alpha-phenylethylamine, the liberated (-)-CPA, also known as alpha-isopropyl-p-chlorophenylacetic acid (ICPA), is treated with an organic solvent selected from dichloromethane, dichloroethane, chloroform, toluene and hexane, and recovery of resolving agent.

**Takuma et al** acknowledge that alpha-phenylethylamine is used as an optical resolving agent from ICPA [page 1, lines 21-23]. **Takuma et al** also teach wide variety of solvents for the isolation of (+)-ICPA and (-)-ICPA, which include toluene, chloroform, and can be mixed with water etc. [page 7, lines 8-21].

The difference between the **Takuma et al** and the instant claims is that **Takuma et al** is silent on the recovery of resolving agent using organic solvent. However, **Yoneyoshi et al** cures this deficiency.

**Yoneyoshi et al** teach the recovery of resolving agent in the process for producing optically active carboxylic acid by using amine as a resolving agent. The crystalline material is separated by filtration, and decomposed with an acid such as

hydrochloric acid, sulfuric acid, thereafter; an extraction operation is carried out with organic solvent to give optically active carboxylic acid. On the other hand, the aqueous layer is alkalinized and subjected to an extraction operation, whereby the (R)- or (S)- isomers of optically active amine compounds may be easily recovered for the reuse thereof [col. 5, lines 22-45]. **Yoneyoshi et al** also teach the use of hydrocarbon solvents for the process for producing optically active carboxylic acid using an amine as a resolving agent [col. 5, lines 10-15].

In summary, **Takuma et al** teach aryl amines as resolving agents for preparing (+)-ICPA and (-)-ICPA from ( $\pm$ )-ICPA using hydrophilic and hydrophobic or mixtures thereof. **Yoneyoshi et al** teach the recovery of resolving agents such as aryl amines in the process for producing optically active carboxylic acids.

Therefore, in view of explicit teachings of references, the examiner asserts that it would have been obvious to a person of ordinary skill in the art, at the time of the invention was made, to have combined the teachings of references to make (+)-2-(4-chlorophenyl)-3-methyl butanoic acid (also known as alpha-isopropyl-p-chlorophenylacetic acid) with a reasonable expectation of success.

Some limitations in the present dependent claims may not be expressly taught in the cited prior art. However, these limitations appear to be drawn to tweaking the composition conditions, particularly concentration ranges, temperature ranges, reaction time etc. Modifying such methodology is prima facie obvious because an ordinary artisan would be motivated to use reaction conditions from the known processes to make the optically active compound more efficient or explore economical advantages

over the other, since it is within the scope to optimize the conditions through routine experimentation. Merely modifying the process conditions such as temperature and concentration is not a patentable modification absent a showing of criticality. In re Aller, 220 F.2d 454, 105 U.S.P.Q. 233 (C.C.P.A. 1955).

### ***Conclusion***

9. No Claim is allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sudhakar Katakam whose telephone number is 571-272-9929. The examiner can normally be reached on M-F 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on 571-272-0871. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Application/Control Number: 10/541,344  
Art Unit: 1621

Page 7

Sudhakar Katakam  
Patent Examiner  
22<sup>nd</sup> Feb 2008

/Karl J. Puttlitz/  
Primary Examiner, Art Unit 1621